



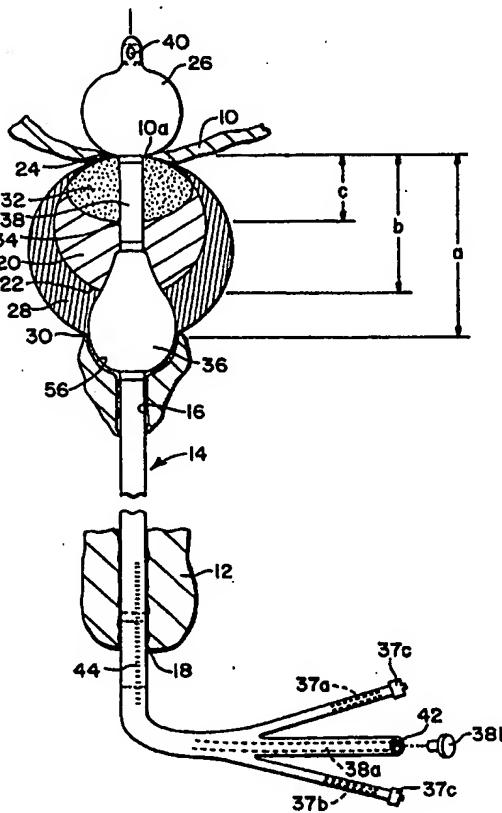
## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> :	A1	(11) International Publication Number: WO 98/51365 (43) International Publication Date: 19 November 1998 (19.11.98)
A61M 29/00		
(21) International Application Number:	PCT/US97/08396	(81) Designated States: AU, CA, JP, KR, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).
(22) International Filing Date:	15 May 1997 (15.05.97)	
(71) Applicant: UROCATH CORPORATION [US/US]; 173 Constitution Park, Menlo Park, CA 94025-1106 (US).		Published <i>With international search report.</i> <i>With amended claims.</i>
(72) Inventor: DAVIS, Richard, C.; 4820 Longwater Way, Tampa, FL 33615 (US).		
(74) Agent: BUTLER, F., Prince; Griffin, Butler, Whisenhunt & Kurtossy, Suite PH-1, 2300 Ninth Street, South, Arlington, VA 22204 (US).		

(54) Title: MALE URETHRAL CATHETER SIZING AND INSERTION METHOD

## (57) Abstract

An indwelling urethral catheter sizing system comprises sets of substantially equal length indwelling urethral catheters (14) having various balloon spacings (a, b, c), from bladder balloons (2) to urethral anchoring cuff balloons (36). A method of implanting an indwelling urethral catheter from the sets involves first determining a patient's interballoon urethral segment length, from his bladder to his bulbous urethra immediately downstream of what remains of his prostate gland. A urethral sizing catheter having a balloon spacing corresponding to the interballoon urethral segment length is inserted in the patient to determine the clinical length of the patient's urethral tract from his bladder to his penile meatus. A male indwelling urethral catheter is then chosen from the sets having a balloon spacing corresponding to the patient's interballoon urethral segment length and the clinical length determined with the urethral sizing catheter. The urethral sizing catheter can be used for filling and voiding the bladder.



**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		
EE	Estonia						

## MALE URETHRAL CATHETER SIZING AND INSERTION METHOD

## BACKGROUND OF THE INVENTION

5        This invention relates to urethral catheters and more specifically to a male indwelling urethral catheter which, after it is inserted and anchored into position, does not extend beyond a patient's penile meatus and allows the patient to urinate in a substantially normal manner.

10      Indwelling urethral catheters of the type to which this invention relates were first disclosed in U.S. patent no. 4,350,161 to Richard C. Davis, Jr. A common feature of such catheters is a valve which, when the catheter is properly anchored in the patient's urethra, is positioned in the patient's penile urethra and can be activated by application of a force external to the penis. A further feature of such a catheter is that it is dimensioned and installed so that its downstream tip does not extend beyond the penis meatus in any patient 15     position. As is set forth in U.S. patent 4,350,161 of Richard C. Davis, Jr. a method of inserting such an indwelling urethral catheter includes the step of determining the length of the patient's urethral tract from his bladder to his penile meatus. Thus, since the advent of the indwelling urethral catheter of the type described above, proper sizing of the catheter has always been appreciated as a critical element in a protocol for positioning the device and in its proper 20     function.

25      During development of this catheter it has come to be better appreciated that as a body moves, a bladder and urethra shift and stretch relative to one another. It has been determined that overall urethral length is generally shortest when a patient is lying down and lengthens when the patient is sitting or standing. Thus, it has been determined that a properly sized male 30     indwelling urethral catheter of this type must be short

enough to remain totally inside the patient's urethra in all positions, but yet long enough to allow easy access to the valve located in the patient's penile urethra for voiding and for removal of the catheter itself.

5 If it is sized too long, the catheter may occasionally protrude from the tip of the penis, potentially causing pain, swelling, and infection. If the catheter is too short, the patient may not be able to easily access the valve to properly actuate it.  
10 Further, the patient may have difficulty removing the catheter.

15 Another feature of the indwelling urethral catheter described in patent no. 4,350,161 to Richard C. Davis, Jr. is that it includes not only a bladder balloon but also an anchoring urethral cuff balloon along a catheter drainage shaft for inflating in the patient's urethra. A primary purpose of the urethral anchoring cuff balloon, as was described in U.S. patent 4,350,161, is to prevent retrograde movement of the catheter into the  
20 bladder by using the prostatic urethra as a buttress against which the urethral anchoring cuff balloon is juxtaposed.

25 To meet different lengths of normal adult urethral tracts, indwelling urethral catheters of the type of this invention, have been, to date, manufactured in six different lengths so that most any length of an adult male penis and urethral tract can be accommodated. However, notwithstanding this, sizing problems continue to be encountered. In this regard, until recently, an  
30 indwelling urethral catheter of the type of this invention was fitted to a patient by first placing a measuring catheter, having a bladder balloon and drainage shaft extending beyond the patient's penile meatus, in the patient. By noting the position of the penile meatus along the measuring catheter's drainage shaft,  
35 with the patient in various positions, the

overall length of the patient's urethral tract was determined. An indwelling urethral catheter was then chosen from the six different lengths corresponding to the overall length of the patient's urethral tract.

5 Using this method, however, problems have continually been encountered in choosing the proper length catheters. That is, after catheters, whose lengths were determined as described above, have been installed it has been found that they often have not remained in their preferred positions. In some cases they have shifted downstream to extend beyond a patient's penile meatus when the patient was in a lying position and in other cases they have shifted upstream so far from the meatus that the patient has not been able to activate the valve to urinate. Because of this, it has sometimes been necessary to try various size catheters in a patient, one after the other -- even though the patient was previously measured -- until a catheter of the correct size, if ever, was found. Thus, in many cases,

10 catheter sizes have actually been determined as much by trial and error as by measuring, if at all. Such trial and error has resulted in discomfort for patients and has proven to be expensive, since it has resulted in the expenditure of many catheters and much time and effort; and often patients were not able to be fitted at all.

15

20

25

The problem has been that some inserted indwelling urethral catheters, of the type of this invention, have experienced undue linear movement along urethral tracts. That is, sometimes they have appeared to be in their correct positions but then at other times they have moved linearly, within the urethral tract, to inappropriate positions. Thus, when some catheters were initially sized using the above-described method, which relied solely on the bladder-to-meatus length, they were occasionally noted to shift downstream in the urethra; thereby appearing to be "too long", and their tips

30

35

intermittently protruded from the penile meatus. It has been assumed that such shifting represented "device failure"; presumably the bladder balloon had leaked thus allowing downstream migration. An opposite situation 5 has been noted in some patients who at first could easily access their valves but who, over time, had increasing difficulty accessing their valves because their catheters migrated upstream. Again, this was previously interpreted as a "device failure" whereby the 10 urethral anchoring cuff balloon was thought to have deflated allowing such upstream migration.

Therefore, it is an object of this invention to provide a system of urethral sizing, or measuring, catheters and a method of its use, which allows accurate 15 measuring of the length of a patient's urethral tract so that an appropriate-length indwelling urethral catheter can be chosen which fits the patient's urethral tract.

Similarly, it is an object of this invention to provide a method for measuring a patient's urethral tract for determining an appropriate clinical length of a indwelling urethral catheter which is accurate, uncomplicated, fast, and not unduly expensive. It is also an object of this invention to provide a system of 20 indwelling urethral catheters which includes sets of urethral catheters of substantially the same lengths but having different features for accommodating patients 25 with different urethral anatomies which vary due to their preexisting clinical conditions.

#### SUMMARY

According to principles of this invention, it has 30 been determined that a cause of this linear shifting is that an anchoring urethral cuff balloon prefers to reside in the bulbous urethra, regardless of its position. It has been thus determined that not only must the overall urethral length be considered, but the 35 distance between the bladder neck orifice and the

bulbous urethra is also critical. This distance is referred to herein as the interballoon urethral segment length.

Further according to principles of this invention, 5 an indwelling urethral catheter system and method of its use involves sets of catheters having substantially the same lengths, but having bladder balloons and urethral anchoring cuff balloons spaced differently from one another in order to accommodate various interballoon 10 urethral segment lengths of patients. Both urethral sizing catheters and indwelling urethral catheters include sets of catheters with variously spaced bladder and urethral-anchoring-cuff balloons.

#### BRIEF DESCRIPTION OF THE DRAWINGS

15 The invention is described and explained in more detail below using the embodiments shown in the drawings. The described and drawn features, in other embodiments of the invention, can be used individually or in preferred combinations. The foregoing and other 20 objects, features and advantages of the invention will be apparent from the following more particular description of a preferred embodiment of the invention, as illustrated in the accompanying drawings in which reference characters refer to the same parts throughout 25 the different views. The drawings are not necessarily to scale, emphasis instead being placed upon illustrating principles of the invention in a clear manner.

30 Fig. 1 is a schematic lengthwise, partially cross-sectional, partially-exploded, view of a single urethral sizing catheter of a set of urethral sizing catheters of this invention when mounted in a patient, with possible prostate sizes being indicated thereon diagrammatically;

35 Figs. 2A-2C are truncated schematic lengthwise cross-sectional views depicting urethral sizing catheters of a urethral sizing catheter set of this

invention with a penis being shown schematically on each of them in cross-section; and,

5 Figs. 3A-3C are schematic lengthwise cross-sectional views depicting indwelling urethral catheters of a set of this invention with a penis being shown schematically on each of them in cross-section.

#### DESCRIPTION OF THE PREFERRED EMBODIMENT

This invention is based on the realization that the distance between the bladder neck orifice and the bulbous urethra, which shall be referenced herein as the "interballoon urethral segment length" and as the "prostatic urethral length", varies tremendously among patients. Such a difference in interballoon urethral segment lengths is illustrated in Fig. 1 where are shown diagrammatically: a patient's bladder 10, the patient's penis 12, and a urethral sizing catheter 14 extending through a urethral tract 16 from the bladder 10 to beyond a penile meatus 18. For purposes of illustration, three different size interballoon urethral segment lengths (i.e. prostate gland or prostate Fossa as the case may be) are represented diagrammatically on Fig. 1. It should be understood that individual patients will have only one of these interballoon urethral segment lengths; however, all three are depicted on Fig. 1 so that a reader can compare the different size interballoon urethral segment lengths with the interballoon spacing (balloon spacing) of a most-often-used (or normal size) sizing catheter and the corresponding indwelling urethral catheter.

30 A normal-size prostate gland 20 has a downstream side 22 which is located approximately four centimeters from the interior surface of a bladder neck orifice 10a (or downstream side 24 of a bladder balloon 26). This four centimeter spacing is represented by the letter "b" 35 in Fig. 1. However, an enlarged, or hypertrophic prostate gland 28 has a downstream side 30 which is

spaced approximately 5.5cm from the downstream side 24 of the bladder balloon 26 in the bladder 10. This 5.5cm measurement is signified by the letter "a" in Fig. 1. Finally, a post prostatectomy prostatic Fossa 32, which is essentially what is left when a prostate is removed (or at least diminished), has a downstream side 34 which is spaced approximately 2.0cm from the downstream side 24 of the bladder balloon 26 when it is in the bladder 10. This downstream side of the bladder balloon 26 can also be influenced to some extent by the position of the bulbous urethra. In this regard, when a patient's prostate is removed, it sometimes happens that some of the bladder must also be removed and reconstructed. In this process, these elements move relative to one another to some extent.

In any event, this 2.0cm measurement is indicated by the letter "c" in Fig. 1. It should be understood that these measurements are only given as approximations and that they can vary significantly from patient to patient. However, it can be seen from these approximations, in Fig. 1, that the relative interballoon urethral segment lengths ("b", "a", & "c") of patients -- and thus necessary catheter balloon spacings -- can vary by a factor of nearly three (comparing "a" with "c").

The urethral sizing catheter 14 is shown as having a urethral anchoring cuff balloon 36 which is spaced along a shaft 38 of the catheter 14 from the downstream side 24 of the bladder balloon 26 thus defining a catheter interballoon distance. Thus, the overall upstream structure of the bladder balloon 26 and the urethral anchoring cuff balloon 36 for this sizing catheter 14 is quite similar to that of an indwelling urethral catheter of the type with which this invention relates.

The bladder balloon 26 and the urethral anchoring

5                   cuff balloon 36, shown in Fig. 1, are spaced from one another a correct amount to appropriately anchor the urethral sizing catheter 14 on the normal-size prostate gland 20, which it inflatingly engages. That is, when  
10                 the bladder balloon 26 and the urethral anchoring cuff balloon are inflated, as shown, they apply pressure to opposite sides of the normal-size prostate gland 20 for holding the urethral sizing catheter 14 against retrograde movement (up into the bladder 10) and against downstream movement (out of the penile meatus 18).

15                 According to this invention, if the patient had an enlarged prostate gland 28, or a missing prostate gland 32 as a result of having prostatectomy surgery, a different respective urethral sizing catheter 14 would be selected, one with its catheter interballoon distance being appropriate so that the balloons impinge on opposite sides of the prostate gland, or prostate fossa as the case may be, on which the urethral sizing catheter is to be mounted. In all cases, however, the  
20                 urethral anchoring cuff balloon resides in the bulbous urethra. In the past, all sizing catheters have had essentially the same balloon configuration. Further, all indwelling urethral catheters have had essentially the same interballoon distance configuration. The  
25                 urethral sizing catheter 14, in addition to having two inflation lumens 37a, 37b -- for inflating the bladder balloon 26 and the urethral anchoring cuff balloon 36 through Robert's valves 37c (see U.S. Patent 5,041,092 to Barwick as well as the previously-described U.S. Patent 4,350,161 to Davis for such disclosures) -- has a drainage/filling lumen 38a which connects bladder openings 40 with an exterior opening 42 (these elements being shown schematically). Using this drainage/filling lumen 38a of the urethral sizing catheter 14, the bladder 10 can be filled and voided.

30                 Further, the urethral sizing catheter 14 has

graduation indicia 44 along its length so that one can "read" the position of the penile meatus 18 along the catheter shaft 38 for determining the appropriate overall clinical length of an indwelling urethral catheter while the patient moves throughout a series of positions and ranges of motion.

Figs. 2A-2C depict a set of urethral sizing catheters 14a-14c. As can be seen in Figs. 2A-2C each urethral sizing catheter of this set has a different interballoon spacing (interballoon) between the bladder balloon 26 and the respective urethral anchoring cuff balloon 36a-c corresponding to a different interballoon urethral segment length "a", "b", "c", thus defining 3 different interballoon spacings.

Figs. 3A-C depict respectively three different indwelling urethral catheters 46a, 46b, 46c of a urethral catheter set. Each of the catheters 46a-46c of the indwelling urethral catheter set generally has a drainage lumen communicating with bladder openings 48 in a Murphy tip 54, a valve 50 for controlling flow through the drainage lumen, and two inflation lumens (not shown) for inflating the bladder balloon 52 and the urethral anchoring cuff balloon 53a-c. The details of this catheter are not described herein inasmuch as the details do not relate to this invention. However, details of such male indwelling urethral catheters can be found in U.S. Patents 4,350,161; 5,041,092; and, 4,932,938.

In any event, it can be seen that each of the indwelling urethral catheters of the set depicted in Figs. 3A-C has approximately the same overall urethral length L. However, the respective spacings between the bladder balloons 52 and the urethral anchoring cuff balloons 53a-c corresponding to interballoon urethral segment lengths a, b, c are quite different for each member of the set.

5                   Describing now a method of fitting an indwelling  
                 urethral catheter of the type of this invention to a  
                 patient, an investigator first determines a patient's  
                 interballoon urethral segment length. The investigator  
10                  does this by examining the patient's medical history to  
                 determine if the patient's prostate gland has not been  
                 removed. If the prostate gland has not been removed,  
                 the investigator determines the size of the patient's  
15                  prostate gland indirectly by rectal exam or directly by  
                 measuring the length of the prostatic urethra using  
                 cystoscopic or ultrasonic methods. By doing this the  
                 investigator can then determine which of the urethral  
                 sizing catheters 36a-c depicted respectively in Figs.  
2A-2C (the one with a balloon spacing corresponding to  
15                  the interballoon urethral segment length of the patient)  
                 should be used. The investigator then:

20                  1. With the patient recumbent, washes the  
                 patient's penis and swabs it with a Betadine solution  
                 using standard sterile techniques and prepping  
                 procedures.

25                  2. Applies an anesthetic lubricant to the  
                 urethral sizing catheter 36a, 36b or 36c which has been  
                 chosen and inserts the catheter, Murphy tip 54 first,  
                 into the patient's bladder through the patient's  
                 urethral meatus 18. The bladder balloon 26 is inflated  
                 with a volume of sterile saline solution through an  
                 inflation valve (not shown) and an inflation lumen (not  
                 shown) and a gentle external axial traction is applied  
                 to the catheter to snug the bladder balloon 26 against  
30                  a base of the bladder neck orifice 10a.

35                  3. While applying continual axial traction, a  
                 volume of sterile saline is instilled through the  
                 inflation (Roberts) valve, thus inflating the urethral  
                 anchoring cuff balloon 36a, 36b, or 36c in the patient's  
                 bulbus urethra 56 (Fig. 1) to the point of mild  
                 discomfort for the patient. (Note that the bulbous

urethra is always the preferred anchoring position of the anchoring cuff balloon 36a-c within the urethra).

5       4. The bladder 10 is then slowly instilled with a volume of sterile saline through the drainage/filling lumen 38a of the urethral sizing catheter 14a, 14b or 14c. The drainage lumen is then occluded with a plug 38b (shown schematically) and the patient is observed from a few minutes up to as long as several days. In some cases it is necessary to fill and 10 void bladders a number of times in order to condition patients who have not had full bladders for a long time, for example.

15       5. Once the patient is able to tolerate the urethral sizing catheter with a full bladder, without discomfort, leakage, spasms, or other difficulties, the operator reads and notes the patient's overall clinical urethral length from the graduation indicia 44 on the urethral sizing catheter at the penile meatus 18 when the patient is in prone, sitting, and standing 20 positions, with little or no traction on the catheter. If any difficulties in the patient are noted, adjustment in balloon volumes can be made to "custom-fit" it for a given patent. The volumes used for inflating the balloons for achieving particular graduation-indicia 25 readings are also noted. The urethral sizing catheter is then removed (after voiding the bladder) by deflating the bladder balloon 26 and the urethral anchoring cuff balloon 36a, 36b or 36c and the urethral sizing catheter is withdrawn from the patient's penis by applying gentle axial traction.

30       6. An indwelling urethral catheter is selected 46a, 46b or 46c having a balloon spacing between its bladder balloon 52 and its urethral anchoring cuff balloon 53a, b, or c which corresponds to the interballoon urethral segment length "a", "b" or "c" as determined above. As stated above, the interballoon 35

urethral segment length "a" normally corresponds to a patient with an enlarged prostate gland, the interballoon urethral segment length "b" normally corresponds to a patient with a normal size prostate gland, and the interballoon urethral segment length "c" normally corresponds to a patient who has had his prostate removed. However, there also exists variations, modifications, and exceptions to these 3 general categories. The catheter chosen also has a length which corresponds to the graduation-indicia reading taken on the urethral sizing catheter. That is, the catheter chosen when inserted and anchored in the patient, would not quite extend along the urethra to the graduation-indicia reading, in all positions of the patient, but yet its downstream tip (and its evacuation valve) are relatively close to the penile meatus in all positions of the patient.

7. The indwelling urethral catheter which has been selected is then inserted and its bladder balloon 52 and urethral anchoring cuff balloon 53a, b or c are inflated sequentially in that order, with the identical volumes as were determined by the sizing catheter.

Sizing is usually required only once and this procedure accurately and efficiently accomplishes a correct sizing of an indwelling urethral catheter on an initial insertion nearly every time. The entire procedure requires less than five minutes, is only slightly uncomfortable, and should not be painful for patients.

Further, any "mis-sizing" of the indwelling urethral catheter will usually be noted immediately after the indwelling urethral catheter has been placed and is certain to be observed within minutes (not days) once the patient is observed to void and to ambulate around the office.

In the past, it has only been necessary to have one

5 type of urethral sizing catheter and six different lengths of indwelling urethral catheters. However, with this new system, it is anticipated that there will be at least three different sizes of urethral catheters, each having approximately the same length but each having different balloon spacings to accommodate the different interballoon urethral segment lengths. Further, it is anticipated that there will now be up to 18 different 10 indwelling urethral catheter sizes. That is, there will still be up to six different overall clinical catheter lengths, but for each length there will be a set of at least three different balloon spacings to accommodate various interballoon urethral segment lengths of patients.

15 It will be appreciated by those of ordinary skill in the art that the method of determining the proper size indwelling urethral catheter, and the unique indwelling urethral catheter sets themselves, of this invention significantly reduce the chance of linear shifting within a urethra, thus improving the operation 20 of male indwelling urethral catheters as well as reducing the time required for sizing them and decreasing discomfort to patients using them. Further, by improving the accuracy of initial sizing, expenses 25 are reduced.

30 An important aspect of this invention is that both overall urethral length and the interballoon urethral segment length must be taken into consideration. Also, changes caused by filling a bladder are also taken into consideration.

35 It should be appreciated by those of ordinary skill in the art that the step of instilling the bladder with a volume of sterile saline through the drainage/filling lumen 38 of the urethral sizing catheter 14, and then occluding the drainage lumen with a plug 38b before the patient is observed and measured, is an important and

new step in the sizing method. In this regard, prior art sizing catheters measured patients without filling their bladders. Many patients, because they are incontinent, were not used to having filled bladders and were unable to tolerate this. Thus, the sizing catheter of this invention provides information to an operator as to the patient's level of tolerance. Similarly, the operator can use the sizing catheter for "exercising" a patient's bladder by filling and voiding the bladder to prepare the patient for using an indwelling urethral catheter. Also, by filling the bladder prior to taken an overall clinical urethral length measurement, a more accurate clinical length is determined. That is, filling a bladder can influence catheter length.

The invention claimed is:

1. A method of determining a clinical length of an indwelling urethral catheter of a type for extending from a male's bladder to close to his penile meatus without extending outside his body, said method comprising the steps of:

5 determining the male's interballoon urethral segment length, from his bladder to a bulbus urethra immediately downstream of what remains of his prostate gland;

10 choosing an elongated urethral sizing catheter having a bladder balloon at an upstream end thereof and a urethral anchoring cuff balloon spaced along the urethral sizing catheter in a downstream direction from the bladder balloon a balloon spacing which corresponds to the patient's interballoon urethral segment length, said urethral sizing catheter having an overall length substantially greater than an overall length of the patient's urethral tract;

15 20 inserting the urethral sizing catheter into the patient's urethral tract and inflating the bladder balloon in the patient's bladder and the urethral anchoring cuff balloon in the patient's bulbus urethra so that the urethral sizing catheter extends outside of the patient's penile meatus;

25 noting the position of the penile meatus on the urethral sizing catheter; and,

30 choosing an indwelling urethral catheter from a set of indwelling urethral catheters -- with each indwelling urethral catheter of the set having different balloon spacings than other indwelling urethral catheters of the set -- having a balloon spacing corresponding to the interballoon urethral segment length of the male and having a clinical length which is less than the length of the male's urinary tract.

2. A method of choosing an indwelling urethral catheter as in claim 1 wherein said set of indwelling catheters

5

includes urethral catheters having approximately the same clinical length but having at least three substantially different balloon spacings corresponding to a normal prostate gland, an enlarged prostate gland, and a diminished prostate gland.

5

3. A method as in claim 2 wherein is further included the step of filling said patient's bladder with liquid through a drainage/filling lumen of said urethral sizing catheter before noting the position of the penile meatus on said urethral sizing catheter.

4. A method as in claim 3 wherein the position of said penile meatus along said catheter is noted while the patient is in a prone position, a sitting position, and a standing position.

5

5. A method as in claim 1 wherein is further included the step of filling said patient's bladder with liquid through a drainage/filling lumen of said urethral sizing catheter before noting the position of the penile meatus on said urethral sizing catheter.

6. A method as in claim 5 wherein the position of said penile meatus along said catheter is noted while the patient is in a prone position, a sitting position, and a standing position.

7. A method as in claim 1 wherein said urethral sizing catheter has graduated markings along its length.

8. A set of urethral sizing catheters each urethral sizing catheter of the set being longer than most patient's urethral tracts, each urethral sizing catheter of the set having a bladder balloon at an upstream end

5 thereof and a urethral anchoring cuff balloon spaced therefrom a balloon spacing along the urethral sizing catheter in a downstream direction, with each urethral sizing catheter of the set having a different balloon spacing from the other urethral sizing catheters in the  
10 set.

9. A set of urethral sizing catheters as in claim 8 wherein said set includes at least three sizing catheters, with each sizing catheter having a different balloon spacing.

10. A set of urethral sizing catheters as in claim 9 wherein all urethral sizing catheters have graduated markings therealong.

11. A set of urethral sizing catheters as in claim 8 wherein all urethral sizing catheters have graduated markings therealong.

12. A set of urethral sizing catheter as in claim 8 wherein each urethral sizing catheter of the set includes a drainage/filling lumen for voiding and filling a bladder and a means for occluding the  
5 drainage/filling lumen.

13. A set of a plurality of indwelling urethral catheters, each urethral catheter of the set including a bladder balloon at an upstream end thereof and an  
10 urethral anchoring cuff balloon spaced along the indwelling urethral catheter in a downstream direction from the bladder balloon a balloon spacing which corresponds to a patient's interballoon urethral segment length, each indwelling urethral catheter of said set having approximately the same length, but each having a  
15 different balloon spacing from the other indwelling

urethral catheters of the set.

14. A set of indwelling urethral catheters as in claim  
12 wherein there are indwelling urethral catheters in  
the set having three different balloon spacings  
corresponding to three different prostatic urethral  
spacings.  
5

15. A set of indwelling urethral catheters as in claim  
13 wherein the three prostatic urethral spacings  
respectively correspond to interballoon urethral segment  
lengths for patients with: a normal prostate gland, an  
enlarged prostate gland, and a removed prostate gland.  
5

16. A method of determining a clinical length of an  
indwelling urethral catheter of a type for extending  
from a male's bladder to close to his penile meatus  
without extending outside his body, said method  
10 comprising the steps of:

choosing an elongated urethral sizing catheter  
having a bladder balloon at an upstream end thereof,  
said urethral sizing catheter having an overall length  
15 substantially greater than an overall length of the  
patient's urethral tract;

inserting the urethral sizing catheter into the  
patient's urethral tract and inflating the bladder  
balloon in the patient's bladder with a downstream end  
20 the urethral sizing catheter extending outside of the  
patient's penile meatus;

filling said patient's bladder with liquid through  
a drainage/filling lumen of said urethral sizing  
catheter before noting the position of the penile meatus  
25 on said urethral sizing catheter;

noting the position of the penile meatus on the  
urethral sizing catheter as corresponding to the length  
of the male's urinary tract; and,

choosing an indwelling urethral catheter having a clinical length which is less than the length of the male's urinary tract as determined from the urethral sizing catheter.

**AMENDED CLAIMS**

[received by the International Bureau on 03 June 1998 (03.06.98)  
original claims 1-16 replaced by amended  
claims 1-17 (8 pages)]

1. A method of determining a clinical length of an indwelling urethral catheter of a type for extending from a male's bladder to close to his penile meatus without extending outside his body, said method comprising the steps of:

determining the male's urethral segment length, from his bladder to a bulbous urethra immediately downstream of what remains of his prostate gland;

choosing an elongated urethral sizing catheter having a bladder expandable retainer at an upstream end thereof and a urethral expandable retainer spaced along the urethral sizing catheter in a downstream direction from the bladder expandable retainer an expandable-retainer spacing which corresponds to the patient's urethral segment length, said urethral sizing catheter having an overall length substantially greater than an overall length of the patient's urethral tract with graduation indicia thereon;

inserting the urethral sizing catheter into the patient's urethral tract and expanding the bladder expandable retainer in the patient's bladder and the urethral expandable retainer in the patient's bulbous urethra so that the urethral sizing catheter extends

outside of the patient's penile meatus;

noting the position of the penile meatus on the urethral sizing catheter relative to the graduation indicia and thereby determining a desired length for an  
5 indwelling urethral catheter; and,

choosing an indwelling urethral catheter having a desired length and having an expandable-retainer spacing corresponding to the urethral segment length of the male and having a clinical length which is less  
10 than the length of the male's urinary tract.

2. A method as in claim 1 wherein said said indwelling catheter is chosen from a set of indwelling catheters which includes urethral catheters having approximately a same clinical length but having at  
15 least three substantially different expandable-retainer spacings corresponding to a normal prostate gland, an enlarged prostate gland, and a diminished prostate gland.

3. A method as in claim 2 wherein is further  
20 included the step of filling said patient's bladder with liquid through a drainage/filling lumen of said urethral sizing catheter before noting the position of

the penile meatus on said urethral sizing catheter.

4. A method as in claim 3 wherein the position of said penile meatus along said urethral sizing catheter is noted while the patient is in at least two of the following positions: a prone position, a sitting position, and a standing position.

5. A method as in claim 1 wherein is further included the step of filling said patient's bladder with liquid through a drainage/filling lumen of said urethral sizing catheter before noting the position of the penile meatus on said urethral sizing catheter.

6. A method as in claim 5 wherein the position of said penile meatus along said urethral sizing catheter is noted while the patient is in at least two of the following positions: a prone position, a sitting position, and a standing position.

7. A method as in claim 1 wherein said sizing catheter is chosen from a set of urethral sizing catheters with each of said sizing catheters of the set having a different expandable-retainer spacing than

that of other sizing catheters of the set and each of said urethral sizing catheters of the set of urethral sizing catheters having graduated markings along its length..

5           8. A urethral-catheter system comprising a urethral sizing catheter for measuring a distance from a patient's bulbous urethra to the patient's penile meatus and an indwelling urethral catheter for controlling flow of urine through the patient's urethra  
10 with a valve therein, wherein;

the urethral sizing catheter has a shaft formed of non-separable parts which is longer than most patients' urethral tracts, the urethral sizing catheter having a bladder expandable retainer at an upstream end of the  
15 shaft, an urethral expandable retainer spaced from the bladder expandable retainer a specified sizing-catheter expandable-retainer spacing, and graduation indicia along the shaft downstream of the expandable retainers;

the indwelling urethral catheter including a valve  
20 therein for controlling urine flow through the indwelling urethral catheter, a bladder expandable retainer at an upstream end thereof, and a urethral

expandable retainer spaced along the indwelling urethral catheter in a downstream direction from the bladder expandable retainer an indwelling expandable-retainer spacing which approximates that of the sizing-  
5 catheter expandable-retainer spacing of the sizing catheter.

9. A urethral-catheter system as in claim 8 wherein said urethral sizing catheter is one of a set of urethral sizing catheters and said indwelling  
10 urethral catheter is one of a set of indwelling urethral catheters, each of said sets including at least three respective sizing and indwelling catheters, with each of the at least three respective sizing and indwelling catheters having a different expandable-  
15 retainer spacing than other members of the set.

10. A urethral-catheter system as in claim 9 wherein all three of the urethral sizing catheters have graduated markings along the shafts thereof to measure the location of a penile meatus.

claim 8 wherein each of the urethral sizing catheters has graduated markings along the shafts thereof to measure the location of a penile meatus.

12. A urethral-catheter system as in claim  
5 8 wherein the shaft of the urethral sizing catheter includes a drainage/filling lumen for voiding and filling a bladder and a means for selectively occluding and voiding the drainage/filling lumen.

13. A urethral-catheter system as in claim  
10 12 wherein said means for selectively occluding can be activated for occluding and voiding from a downstream end portion of said shaft.

14. A set of a plurality of indwelling urethral catheters, each urethral catheter of the set including a bladder expandable retainer at an upstream end thereof and a urethral expandable retainer spaced along the indwelling urethral catheter in a downstream direction from the bladder expandable retainer an expandable-retainer spacing which corresponds to a patient's prostatic urethral segment length, each indwelling urethral catheter of said set having approximately the same length, but each having a different expandable-retainer spacing from the other indwelling urethral catheters of the set.

15. A set of indwelling urethral catheters as in claim 14 wherein there are indwelling urethral catheters in the set having three different expandable-retainer spacings corresponding to three different prostatic urethral segment lengths.

16. A set of indwelling urethral catheters as in claim 15 wherein the three prostatic urethral segment lengths respectively correspond to prostatic urethral segment lengths for patients with: a normal prostate gland, an enlarged prostate gland, and a removed prostate gland.

17. A method of determining a clinical length of an indwelling urethral catheter of a type for extending from a male's bladder to close to his penile meatus without extending outside his body, said method comprising the steps of:

choosing an elongated urethral sizing catheter having a bladder expandable retainer at an upstream end thereof, said urethral sizing catheter having an overall length substantially greater than an overall length of the patient's urethral tract;

inserting the urethral sizing catheter into the patient's urethral tract and inflating the bladder expandable retainer in the patient's bladder with a downstream end the urethral sizing catheter extending outside of the patient's penile meatus;

filling said patient's bladder with liquid through a drainage/filling lumen of said urethral sizing catheter before noting the position of the penile meatus on said urethral sizing catheter;

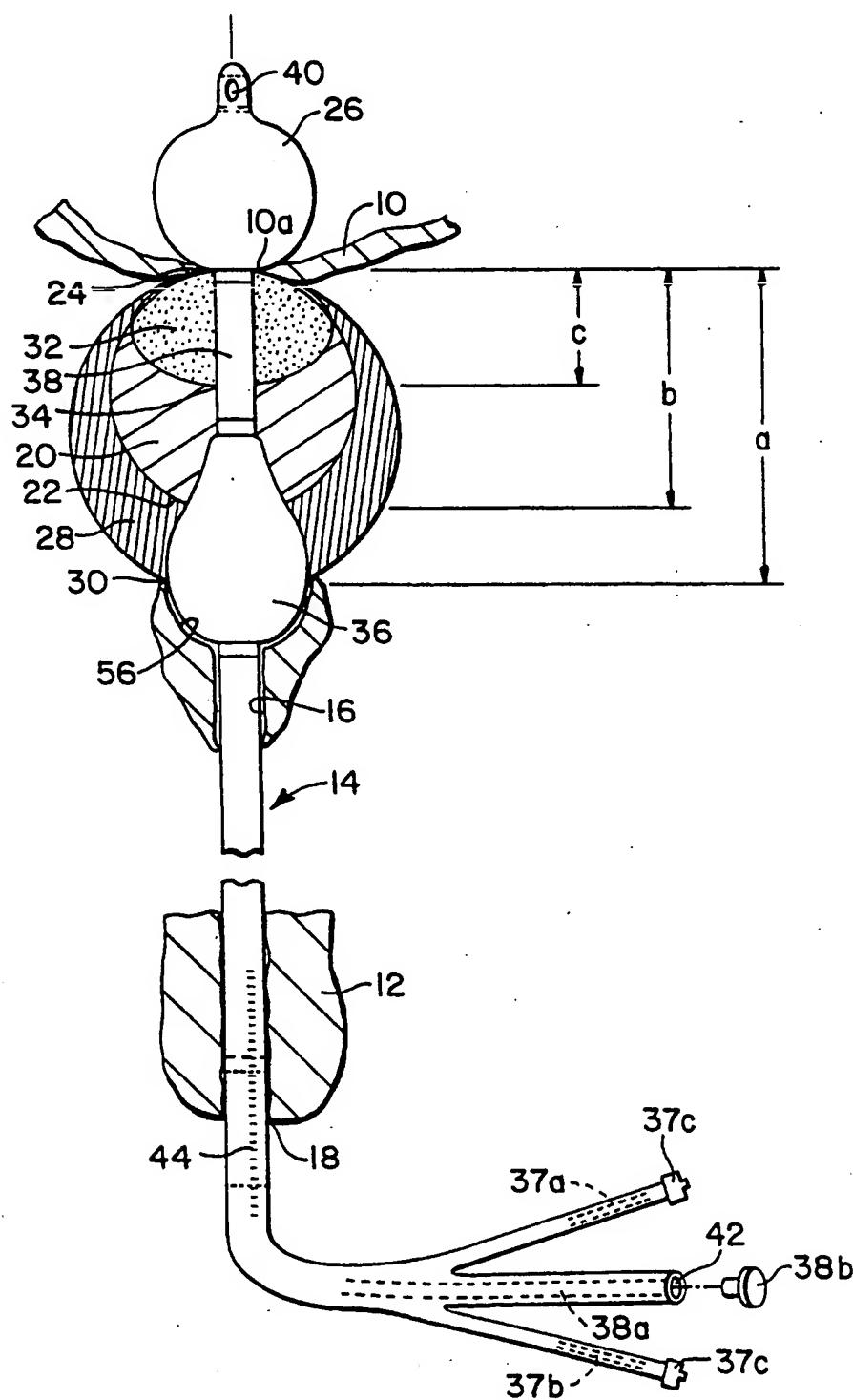
noting the position of the penile meatus on the

urethral sizing catheter as corresponding to the length of the male's urinary tract; and,

choosing an indwelling urethral catheter having a clinical length which is less than the length of the male's urinary tract as determined from the urethral sizing catheter.

1 / 3

## FIG. I



2 / 3

FIG. 2A

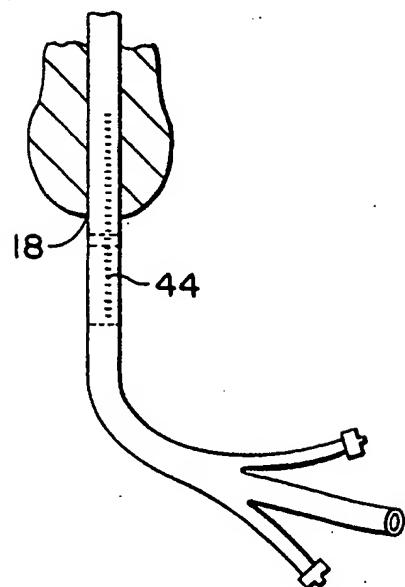
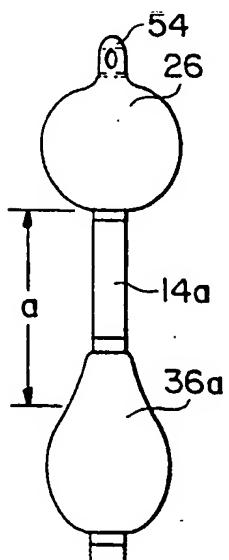


FIG. 2B

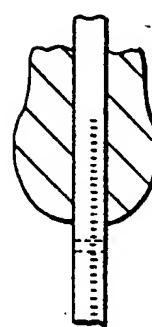
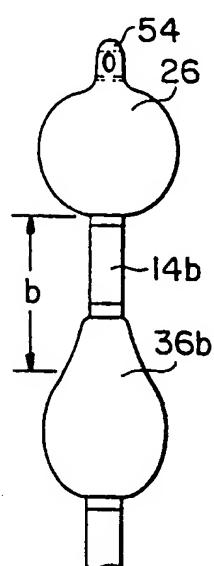
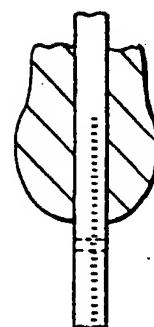
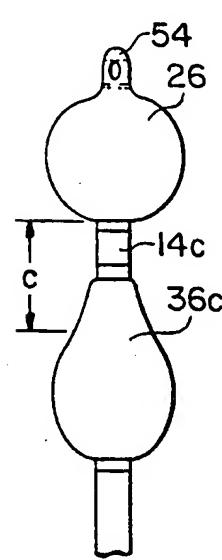
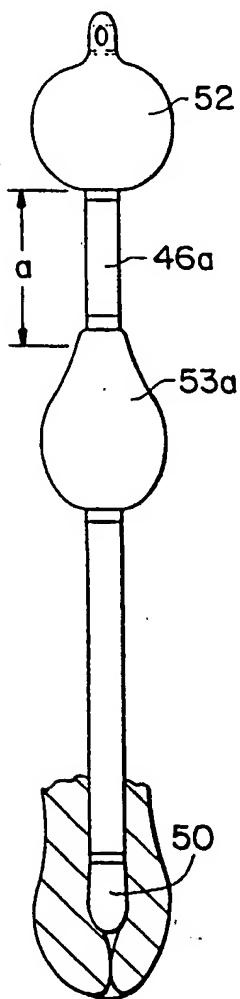
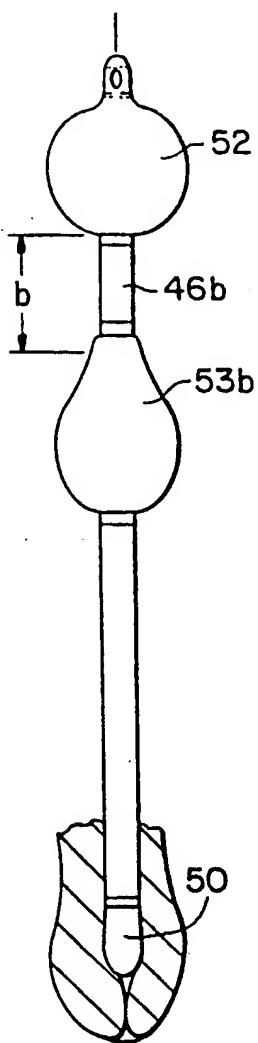
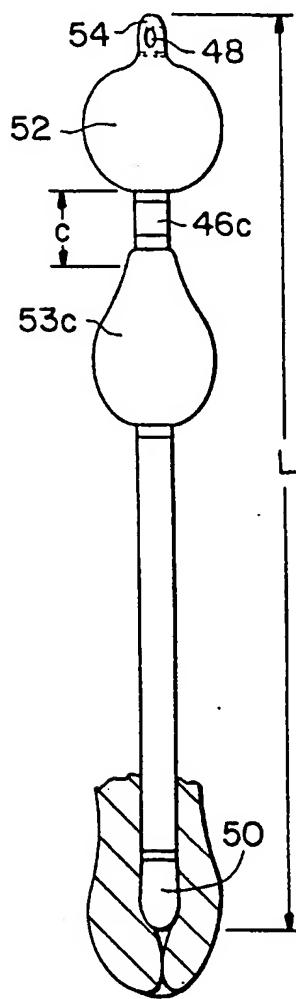


FIG. 2C



3 / 3

**FIG. 3A****FIG. 3B****FIG. 3C**

## INTERNATIONAL SEARCH REPORT

International application No.  
PCT/US97/08396

## A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61M 29/00  
US CL : 604/96

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 604/49, 53, 54, 96-103

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

APS, STIC

Search Terms: method, catheter, urethra, balloon

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	US 4,932,938 A (GOLDBERG et al.) 12 June 1990, Abstract.	8-15
A	US 4,813,935 A (HABER et al.) 21 March 1989, Abstract	1-16
A	US 5,002,558 A (KLEIN et al.) 26 March 1991, Abstract.	1-16

Further documents are listed in the continuation of Box C.  See patent family annex.

* Special categories of cited documents:	"T"	later documents published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A" document defining the general state of the art which is not considered to be of particular relevance		
"E" earlier document published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubt on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&"	document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search

31 JULY 1997

Date of mailing of the international search report

26 AUG 1997

Name and mailing address of the ISA/US  
Commissioner of Patents and Trademarks  
Box PCT  
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

DEBORAH BLYVEIS

Telephone No. 308-2110